Exhibit 2

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Kathryn L. Tucker, Esq.
Emerge Law Group
621 S.W. Morrison Street
Portland, Oregon 97205
kathryn@emergelawgroup.com

Dear Kathryn Tucker:

This letter is in response to your letter dated January 15, 2021, to the Drug Enforcement Administration (DEA). In your letter you state that you are counsel to Advanced Integrative Medical Science Institute and its co-director, Sunil Aggarwal, M.D. You state that Dr. Aggarwal is a palliative care specialist who treats patients with advanced cancer and currently holds a DEA registration as a practitioner. Dr. Aggarwal seeks additional authorization or additional registration (from DEA) to obtain psilocybin, a schedule I controlled substance, for therapeutic use for terminally ill cancer patients suffering anxiety and/or depression. You state that Dr. Aggarwal seeks such authorization pursuant to the "Right to Try Act" (RTT), officially designated as the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. You ask DEA for guidance on how DEA will accommodate the RTT, so that Dr. Aggarwal may obtain psilocybin for therapeutic use with terminally ill patients. DEA appreciates the opportunity to address your request.

DEA understands and appreciates the intent of the RTT, that is, to provide easier access to experimental drugs to patients afflicted with terminal illness. However, absent an explicit statutory exemption to the Controlled Substances Act (CSA), DEA has no authority to waive any of the CSA's requirements pursuant to the RTT. As is made clear in 21 U.S.C. 360bbb-0a(b), excerpted below, the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations.

> *(b) Exemptions*
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> *Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.*

A potential avenue for Dr. Aggarwal to pursue is to apply for a schedule I researcher registration with DEA to conduct research with psilocybin, a schedule I controlled substance. The procedures for such application are outlined in 21 U.S.C. 823(f), 21 CFR 1301.18, and 21 CFR 1301.32.

Finally, in your email to DEA, sent on February 2, 2021, you inquire as to the possibility of DEA issuing an exemption from prosecution to Dr. Aggarwal. You state in your email that this would be akin to the exemption provided for in 21 CFR 1316.24, titled, "Exemption from prosecution for researchers." The exemption provided in this regulation, however, only applies to individuals already registered with DEA to engage in research in controlled substances. *See* 21 CFR 1316.24(a) ("Upon registration of an individual to engage in research in controlled substances . . . the Administrator . . . may exempt the registrant when acting within the scope of his registration, from prosecution . . ."). It would therefore not be applicable to Dr. Aggarwal at this time. Should Dr. Aggarwal obtain a schedule I researcher registration from DEA, he may then petition the DEA Administrator for a grant of exemption from prosecution following the procedure set forth in 21 CFR 1316.24(b).

I trust this letter adequately addresses your inquiry. For additional information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have additional questions regarding this issue, please contact the Policy Section at (571) 362-3260.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division